



UNITED STATES PATENT AND TRADEMARK OFFICE

en
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,575	04/05/2001	Charles E. Loomis	HO-P02054US1	3001
26271	7590	03/23/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			CYGAN, MICHAEL T	
			ART UNIT	PAPER NUMBER
			2855	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/826,575	Applicant(s) LOOMIS ET AL.	
	Examiner Michael Cygan	Art Unit 2855	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004 and 17 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-16, 22-26, 32-52 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-16, 22-26, 32-52 and 57-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the mylar bag and laminated structure must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 58 is objected to because of the following informalities: in the last line, the word "more" appears to be missing but required. Appropriate correction is required.
3. While the copy of the claims lists claims 17-21 as being cancelled, the remarks list them as being pending. The copy of the claims takes precedence, and these claims are cancelled by the amendment of 12 January 2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 5, 9-14, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241). OSHA discloses a sealed testing apparatus comprising a bulb (i.e., a pump) and a container portion (smoke tubes) having frangible ends, an outlet, and containing a chemical substance such as stannic chloride (SnCl_4) producing an "irritant smoke" upon exposure to air. The apparatus produces smoke used to check for leaks in equipment such as face seals, the smoke carrying an irritating scent noticeable by the equipment wearer. OSHA further discloses providing such an apparatus, storing a chemical having a selected scent in the apparatus prior to use, breaking an end portion, causing a chemical reaction between the chemical and air (the local environment), and operating a bulb to start a smoke test, and directing the smoke outward of the container and towards equipment such as a face seal. The smoke is visually observed as the test operator visually directs the smoke in three circumferential passes at a specified distance from the face seal. See page 227.

OSHA teaches the claimed invention except for an integral tube-pump design and the method of forming that design. Garren '241 teaches that it is

known to assemble and use plastic tube-pump integral (one piece) pipettes wherein the pump is seamlessly joined to the tube (Figures 1-3) in place of glass/rubber bulb pipettes (columns 1-2) to form a substantially permanent structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form an integral plastic pipette and use an integral plastic pipette as taught by Garren '241 in place of the two piece pipette disclosed by OSHA, since this would allow operation of the protocol without danger of untimely glass breakage, reduced cost, and reduced assembly time (Garren column 1, line 48 through column 2, line 17).

5. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241) as applied to claims 1, 17, and 22, further in view of U. S. Patent Number 5,073,347 (Garren '347). OSHA teaches the claimed invention except for the plastic being low-density polyethylene, or may be two different materials for bulb and tube. Garren '347 teaches the composition of a plastic pipette being low-density polyethylene or two different materials for bulb and tube (column 9. lines 41-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use low-density polyethylene or two different materials for bulb and tube as taught by Garren '347 in the invention taught by OSHA, since Garren

teaches that such materials are inexpensive and resistant to contamination and breakage during transportation (column 1, lines 38-51).

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over OSHA in view of U.S. 3,834,241 (Garren '241) as applied to claim 1, further in view of Rodrigues (US 3,938,392). OSHA in view of Garren '241 discloses a testing apparatus comprising a bulb (i.e., a pump) and a container portion (smoke tubes) having frangible ends and containing a chemical substance producing an "irritant smoke" upon exposure to air. The apparatus produces smoke used to check for leaks in equipment such as face seals. See page 227. OSHA teaches the claimed invention except for an integral tube-pump design having a finger hole in the pump area. Rodrigues teaches the provision of a finger hole in a flexible plastic pipette bulb (Figure 1) which is used as an improvement over the known glass/rubber two piece bulb (column 1, lines 5-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a finger hole as taught by Rodrigues in the invention taught by OSHA in view of Gerren, since this would allow operation of the protocol without danger of untimely glass breakage (see Rodrigues column 1, lines 11-12) or human injury (see OSHA page 277 lines 6-10) caused by operation of a two piece system having a class component.

7. Claims 8, 16, 32-46, 52, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241) as applied to claims 1, 17, and 22, further in view of U. S. Patent Number 3,840,009 (Michaels). OSHA teaches the claimed invention except for the composition of the device being a laminate of two distinct material layers, one of which being a flexible (low-density) polyethylene, the other comprising a material which may be mylar (an inert, low-permeability material which is inherently substantially more impermeable than the polyethylene). Michael teaches a vapor delivery device in which the plastic pump and tube are formed of polyethylene laminates, one of which may be a polyethylene-Mylar laminate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyethylene laminates including a polyethylene-Mylar laminate as taught by Michael in the invention taught by OSHA to form the casing material, since this will achieve both flexibility and substantial impermeability (see Michaels column 7, lines 49-52 and column 8, lines 1-7) of the device.
8. Claims 36, 48, 49, 51, 58, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241) as applied to claims 1, 17, and 22, further in view of U. S. Patent Number 5,302,344 (Perlman). OSHA teaches the claimed invention except for the packaging of a pipette in a

laminate bag. Perlman discloses laminate metal foil packaging film (inherently substantially more fluid impermeable than a polymer such as polyethylene) for wrapping pipettes; see column 8, lines 1-39. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a laminate packaging film as taught by Perlman in the invention taught by OSHA to package the pipette, since Perlman teaches that the laminates provide a sterile storage which prevents contamination prior to use.

9. Claims 50 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241) and in view of U. S. Patent Number 5,302,344 (Perlman) as applied to claims 36 and 58, further in view of U. S. Patent Number 6,098,802 (Asa). OSHA in view of Garren and Perlman teaches the claimed invention except for the packaging of a pipette in a mylar bag. Asa teaches that mylar is an equivalent packaging material to metal foil for the purpose of maintaining sterile pipettes; see column 5, line 64 through column 6, line 8. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use mylar as the packaging material in the invention taught by OSHA in view of Garren and Perlman to form an inert packaging, since Asa teaches that mylar is an equivalent

packaging material to metal foil (as taught by Perlman) for the purpose of maintaining sterile pipettes.

10. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol (OSHA) in view of U. S. Patent Number 3,834,241 (Garren '241) and in view of U. S. Patent Number 3,840,009 (Michaels) as applied to claims 36, further in view of U. S. Patent Number 3,938,392 (Rodrigues). OSHA teaches the claimed invention except for an integral tube-pump design having a finger hole in the pump area. Rodrigues teaches the provision of a finger hole in a flexible plastic pipette bulb (Figure 1) which is used as an improvement over the known glass/rubber two piece bulb (column 1, lines 5-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a finger hole as taught by Rodrigues in the invention taught by OSHA in view of Gerren, since this would allow operation of the protocol without danger of untimely glass breakage (see Rodrigues column 1, lines 11-12) or human injury (see OSHA page 277 lines 6-10) caused by operation of a two piece system having a glass component.

Response to Arguments

Applicant's arguments filed 24 June 2003 have been fully considered but they are not persuasive. Applicant argues that (page 8):

11. "the pipette portion [of Garren] cannot be sealed as required by the present invention (without defeating the dispensing purpose of the pipette)."

However, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The primary reference (OSHA) teaches a sealed pipette; Garren is applied to teach the prior use and desirability of a plastic pipette over a glass pipette. Note that Garren further notes that the plastic is inert, and therefore would pose no problem in operating with a reactive substance (as argued at page 15, 2nd full paragraph).

12. "no motivation or incentive has surfaced to modify or deviate" from the "two-piece squeeze pump-glass tube design" (page 8). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed.

Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, motivation was presented in the rejection, “this would allow operation of the protocol without danger of untimely glass breakage, reduced cost, and reduced assembly time (Garren column 1, line 48 through column 2, line 17).”

13. “users concerned with the smoke tube art”... “will not look to or necessarily happen upon, the teachings of the pipette art.” It has been held that a prior art reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, it is noted that the smoke tube is a sealed pipette filled with a substance, and therefore the pipette art would certainly be reasonably pertinent to the particular problem with which the applicant was concerned. Note that the motivation for applying the teaching from the pipette art included “reduced cost” and operation “without danger of untimely glass breakage”; this certainly is pertinent to the smoke tube art which the applicant characterizes as “primarily concerned with minimizing cost and risk” (see applicant’s response page 9).

14. "no reasonable expectation of success" (pages 9-10). In addition to the above presented arguments, Garren explicitly recites the expected benefits of replacing a two-piece squeeze pump-glass tube design with a plastic design at a section (column 1, lines 39+) cited in the rejection.
15. The Perlman reference does not teach "a laminate that substantially encases the pump-container portion structure"; instead, teaching only "prepackaging that is removed prior to an autoclaving process" and is "directed to laboratory equipment, which is not the relevant art" (page 10). Perlman discloses such a laminate enclosing an entire pipette (column 8, lines 1-39). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., not prepackaging and not laboratory equipment) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
16. Applicant's supplementary submission of 17 March attempts to show that the OSHA reference describes a state of the art smoke tube, which teaches away from any alteration of the design due to its designation as the standard design, and further, exhibits the failure of others to alter the design in the face

of a long felt need. While the factors of “teaching away” and “long felt need” are of concern in patentability, the OSHA reference exhibits neither.

To “teach away”, the reference must describe a specific feature of the claimed invention and state its unsuitability as a modification of the invention disclosed in the reference. OSHA does not include such a statement. The *Gillette* case cited in the supplementary response is not applicable since the quotation applies to a different factual basis; in *Gillette*, the combination would “discourage” substitution of an article because the court ruled that the original article was critical to the proper function of the original composition. In the present case, applicants argue a disincentive based upon the established success of a previous design, not the criticality of any element of that previous design, and therefore the findings of the case are not applicable.

To demonstrate a “long felt” or “unmet” need, a specific need must be addressed and factually supported; neither occurs in applicant’s response beyond a general statement alleging “much discussion and debate” (page 4). To be given weight in a determination of patentability, facts should be presented (here, in the form of an affidavit or similar) which describe the specific “need” and provide a showing that it has been recognized as unmet. Note the factual basis provided in the *In re Mahurcar* case cited in the supplementary response.

Conclusion

17. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Cygan whose telephone number is (571) 272-2175. The examiner can normally be reached on 8:30-6 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Lefkowitz can be reached on 571-272-2180. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 2855

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Michael Cygan", with a stylized flourish at the end.

Michael Cygan
Primary Examiner
Art Unit 2855